

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

## 1. Purpose

**a) In layperson's language state the purpose of the study in 3-5 sentences.**

To test the efficacy of a breathing meditation treatment (SKY: Sudarshan Kriya Yoga) for post-traumatic stress disorder (PTSD) in veterans. Patients will be assigned to the SKY group or a standard treatment group (CPT: Cognitive Processing Therapy). At the end of the 6-week treatment programs participants will be evaluated again at one month and one year to gain an understanding of whether the SKY treatment has an enduring benefit.

**b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.**

1. To evaluate whether PTSD symptom severity are reduced following treatment with SKY (Sudarshan Kriya Yoga) and to determine whether this change is clinically no different to that produced by a standard treatment (noninferiority hypothesis).
2. To determine if dropout rates of SKY are higher than a standard treatment (Cognitive Processing Therapy).
3. To determine whether improvements in clinical measures of PTSD correlate with improvements in memory consolidation, reflecting improvements in sleep following treatment.
4. To determine whether baseline characteristics predict the efficacy of treatment.

The findings will provide evidence for the efficacy of SKY in treating Veterans with PTSD. As the project also addresses possible mechanisms of action of the treatments, the results will also provide basic insights into the origins of PTSD.

**c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)**

The purpose of the study is to test the efficacy of treatments in individuals with post-traumatic stress disorder.

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

## 2. Study Procedures

- a) Please SUMMARIZE the research procedures, screening through closeout, which the human subject will undergo. Refer to sections in the protocol attached in section 16, BUT do not copy the clinical protocol. Be clear on what is to be done for research and what is part of standard of care.

i) Screening and Randomization (Pre Week 1)

ii) Treatment--Yoga Treatment Group or Pain Support Group (Week 1-6)

iii) End of study (week 6-7)

iv) Follow ups (weeks 11, 63)

Consent and screening (pre-Week 1)

- PCL-5 (PTSD check list-5)

- M.I.N.I. (Mini-International Neuropsychiatric Interview)

Randomization and Baseline Visit (Week 1)

Participant randomized to SKY or CPT Group.

- PCL-C (Posttraumatic Stress Disorder Checklist-Civilian Version)

- (CAPS-V) Clinician Administered PTSD Scale

Overnight memory consolidation measures

Medical History

- Demographics questionnaire

Beck Depression Inventory (BDI-II)

Difficulties in Emotion Regulation Scale (DERS)

Valuing Questionnaire

- BSS (Beck Scale for Suicide Ideation)

- PANAS (The Positive Affect-Negative Affect Schedule)

- "CANTAB" computerized neuropsychological tests

- Spatial Working Memory

- Rapid Visual Processing

- Paired Associates Learning

- Motor Screening

- Heart rate monitoring. Participants will wear a heart rate monitor

for 24 hrs and will return it the following day.

Sleep Actigraphy. Participants will wear an Actigraph monitor for 24

hrs and will return it the following day.

- MAPI (Multivariate Apnea Prediction Index)

- RLS-DI (Restless Legs Syndrome Diagnostic Index)

- CEQ Questionnaire

OPTIONAL MEASURES

- MRI

- EEG

- Polysomnographic sleep recording device; Siesta This is a multi-parametric test used to study of sleep.

Polysomnography is a comprehensive recording of the biophysiological changes that occur during sleep.

Participants will use the recording devices over night. The device monitors many body functions including brain (EEG), eye movements (EOG), muscle activity or skeletal muscle activation (EMG) and heart rhythm (ECG) during sleep.

Treatment (Week 1-6)

SKY (Sudarshan Kriya Yoga) Treatment Group

An experienced and licensed SKY instructor will provide the

treatment. The treatment will be group-based and the group will meet

at the VA Palo Alto for (3 hours/day intensive format) for five days,

followed by five weeks of sessions twice per week (1hr/session). SKY

meditation is a standardized, manual-based program that includes

---

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

---

relaxation techniques as well as periods of discussion. SKY meditation incorporates several types of breathing exercises involving arousal and attentional control. Initial breathing exercises are calming and focusing. Subsequent breathing exercises are more fully engaging energizing, allowing the practitioner to focus more fully in each moment. Participants will be encouraged to learn all the breathing exercises, and to utilize the exercises that seem most appropriate for their needs. After training, participants will be encouraged to seek those venues that they have been avoiding in order to practice the SKY techniques in those environments. They start with situations that are less arousing, and progress to more difficult situations. At each class participants will describe their experiences, and discuss ways to continue to incorporate the SKY exercises into their daily lives, until it becomes natural for them to utilize these skills throughout the day, both in practice, and in application.

Participants will wear a heart rate monitoring device for 24 hours on 2 occasions (baseline, end of treatment). They will be fitted with the heart rate monitor 30 minutes before the yoga class begins and will be asked to keep wearing it for the next 24 hours. They will return it on their next visit. We will use a device sold by Camntech Ltd. It is non-invasive, light weight, and unlikely to cause any distress other than irritation by the non-allergenic electrode gel if needed.

CPT-C (Cognitive Processing Therapy-"Cognitive Only")Treatment Group  
CPT-C will be provided by a licensed clinical psychologist. It is a standard manualized therapy provided by the VA to treat PTSD. CPT-C will be delivered individually over 12, 60-minute sessions twice per week. Sessions will include reviewing homework from the previous session, focusing on specific issues, learning new therapeutic techniques and setting up homework for the following session including real-life application of learned CPT techniques  
Sessions 1 - 4; patients are educated regarding the theory behind CPT and asked to explore the "meaning" of their traumas. Patients are taught the connection between events, thoughts, and feelings and begin to identify places where they have become "stuck" in their thinking. Sessions 5 - 7, the core cognitive therapy skills are taught, including looking at the evidence for and against their "stuck" beliefs, examining the context from which the belief was formed. Session 6, patients become familiar with common faulty thinking patterns that can interfere with recovery from PTSD e.g., overgeneralizing from a single incident. Sessions 8 - 12, patients focus on five key areas, including safety, trust, power/control, esteem, and intimacy. Session 12, patients look to the future and identify areas that may be problematic and discuss ways that they can manage these issues. In the CPT-C version, no traumatic accounts are written.

Weeks 1-6 (All participants)

- Homework and log (week 1 through 6). Daily log to record home practice of intervention, estimated hours of sleep, and medication changes.

Follow-up (Weeks 11 and 63)

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

•PCL-C  
BDI-II  
•PANAS  
Valuing Questionnaire

Follow-up (Week 63)  
One Year Reflection Form

**b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.**

Delaying treatment for PTSD is problematic as such patients are at relatively high risk for suicide and symptoms can worsen, or suicidal or homicidal intent may arise at any time. Although wait list control designs provide some benefit to patients with PTSD, current best research practices stipulate that such patients receive treatment without delay. The noninferiority design chosen for this study is consistent with this concept because all participants are given treatment for PTSD without a delay. Furthermore, psychotropic medications are allowed during the study and are monitored as an outcome variable.

**c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).**

No deception used.

**d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.**

Video recording will be used to monitor treatment fidelity. Recordings will be made of treatment providers, and not the participants. All recordings will be stored indefinitely in accordance with VA guidelines.

**e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).**

Alternative procedures or courses of treatment for PTSD fall into two categories; pharmacological and behavioral. Ongoing pharmacological treatment will be accommodated in the trial by allowing patients who have been receiving a stable course (no change for the prior eight weeks) of psychotropic medication to continue to take the medication.

For behavioral interventions, patients will be ineligible for the study if they intend to begin a new psychological treatment (e.g., Cognitive Behavioral Therapy including Prolonged Exposure or Cognitive Processing Therapy) during the study period. We believe this is reasonable given that the study interventions are behaviorally-based and includes a manualized Cognitive Processing Therapy as one of the treatment arms. It should be noted that a wait-list control is not being used, and patients will potentially benefit from either treatment arm of the study. This study design seeks to minimize the risks of being in the study while maintaining scientific integrity.

**f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the**

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

### conclusion of the study?

Participants will be encouraged to continue any therapy they find beneficial after the conclusion of the study.

- g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?**

Monitoring will begin evaluating data every 3 months once enrollment begins. However, this is a noninferiority design, and it is expected that both treatment arms will show similar efficacy. This determination cannot be made with statistical accuracy before 76 participants have been recruited and completed the study.

## 3. Background

- a) Describe past experimental and/or clinical findings leading to the formulation of the study.**

Meditation-based treatments are widespread in VA Hospitals and other community institutions for Veterans. Research suggests that they can provide effective relief from anxiety symptoms while improving psychological well-being. There is evidence that SKY is effective in treating PTSD. For example, patients with PTSD from sexual abuse reported reduced arousal, anxiety and hypervigilance when SKY was combined with traditional psychiatric and psychological therapies (Sageman & Brown, 2006). In another study, survivors from the 2004 Indian Ocean tsunami were assigned to SKY, or SKY in combination with exposure therapy or a 6-week wait list (Descilo et al., 2010). After participants who were given SKY had significantly reduced scores on the PCL compared to the wait list control group. Treatment effects were maintained at a 24 week follow-up. There were no significant differences between the SKY group and the SKY in combination with exposure therapy group, a result that underscores the potential strength of SKY as a stand-alone intervention.

Little research exists on the effects of SKY on combat Veterans with PTSD. In a pilot randomized controlled study of 32 Australian Veterans with PTSD, those given a 5-day course of SKY showed statistically significant reductions on the Clinician Administered PTSD Scale (CAPS) of 14.2 points (Brown, Gerbarg, & Muskin, 2009). The wait-list group showed no significant decline. Benefits of treatment were maintained at 6-week and 6-month follow-ups with average CAPS scores in the treatment group of about 20 points lower than at baseline. The Veterans also learned how to use the yoga breathing to calm down in their daily lives and indices of depression improved and alcohol consumption declined.

Dr. Seppala (Investigator) recently conducted a preliminary intervention study using SKY in 20 combat Veterans (Seppälä EM, et al. Breathing-Based Meditation Decreases Posttraumatic Stress Disorder Symptoms in U.S. Military Veterans: A Randomized Controlled Longitudinal Study. *Journal of Traumatic Stress*. 2014;27(4):397-405).

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

). PTSD symptoms were measured using the PTSD check list. Participants were randomly assigned to a SKY group or a wait-list control. Participants in the SKY group were given a 7-day SKY workshop. Results showed improvements in the SKY group compared to the waitlist control group on multiple measures including overall PTSD symptoms, anxiety as measured by the STAI, and sleep quality as measured by the PSQ, and spatial working memory. The effects of SKY on anxiety and depression remained significant one month after, and one year after the intervention.

In summary, pilot data provide evidence that SKY can treat arousal and attentional control mechanisms in PTSD. Some limitations of previous research are that participants did not all reach criterion for PTSD, SKY was not compared to current best practice treatments, and small sample sizes limits generalization to other populations.

The current study is formulated to following up on these pilot observations, especially in the domains of PTSD symptoms, anxiety and sleep disturbance.

**b) Describe any animal experimentation and findings leading to the formulation of the study.**

None

#### 4. Radioisotopes or Radiation Machines

- a) List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Identify Week/Month of study	Name of Exam	Identify if SOC or Research
------------------------------	--------------	-----------------------------

- b) For research radioisotope projects, provide the following radiation-related information:

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

- c) For research radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

---

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder**Approval Period:** 11/30/2020 - 11/30/2021

---

**d) For research radiation machine projects, provide the following therapeutic procedures:**

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participants's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

**5. Devices****a) Please list in the table below all Investigational Devices (including Commercial Devices used off-label) to be used on participants****b) Please list in the table below all IDE Exempt Devices (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices) to be used on participants.****5.1 Device Name : Actiheart****Describe the device to be used.**

The Actiheart is a compact, chest-worn monitoring device that records heart rate, Inter-Beat-Interval (IBI), and physical activity in a combined, light-weight waterproof unit.

**Manufacturer :** CamNtech Ltd**IDE Exemption**

Y This is a legally marketed device being used in accordance with its labeling.

**5.2 Device Name : Motionlogger Watch****Describe the device to be used.**

Actigraph Motionlogger Watch

**Manufacturer :** Ambulatory Monitoring Inc**IDE Exemption**

Y This is a legally marketed device being used in accordance with its labeling.

**5.3 Device Name : 3T GE Discovery MR750****Describe the device to be used.**

MRI Scanner

**Manufacturer :** General Electric**IDE Exemption**

Y This is a legally marketed device being used in accordance with its labeling.

**5.4 Device Name : Neuroscan EEG**



---

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder**Approval Period:** 11/30/2020 - 11/30/2021

---

**Describe the device to be used.**

Electroencephalogram

**Manufacturer :** Neuroscan**IDE Exemption**

Y This is a legally marketed device being used in accordance with its labeling.

**5.5 Device Name : Siesta****Describe the device to be used.**

Polysomnographic sleep recording device

**Manufacturer :** Compumedics**IDE Exemption**

Y This is a legally marketed device being used in accordance with its labeling.

**6. Drugs, Reagents, or Chemicals and Devices**

- a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to participants.
- b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to participants.

**7. Medical Equipment for Human Subjects and Laboratory Animals**

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.

None

**8. Participant Population**

- a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

(i) 76 participants are expected to be enrolled  
(ii) 76 participants at VAPAHCS  
(iii) A novel treatment for PTSD is being evaluated. Therefore all participants will have symptoms of PTSD.

- b) State the age range, gender, and ethnic background of the participant population being recruited.

Age range: aged 18 years or older  
Gender: Males and Females  
Ethnic Background: Any race or ethnic origin

- c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the



**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

**risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.**

Children, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people will not be recruited.

- d) If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).**

There will be no participation of children in this study as they would not be veterans.

- e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy.**

It is unlikely that any laboratory personnel, employees, or students will qualify for participation in this study. If any do qualify and wish to participate, they will be treated the same as any other participant.

- f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.**

Participants should all be in fair physical health though with the stated symptoms of PTSD. All procedures are considered low risk or standard of care.

- g) How will you identify and recruit potential participants about the research study? (E.g., by: chart review; notified by treating physician; response to ad). All final or revised recruitment materials, flyers, etc. must be submitted to the IRB for review and approval before use. You may not contact potential participants prior to IRB approval. See Advertisements: Appropriate Language for Recruitment Material.**

Potential participants will recruited through three sources.

1. CLINCS: Palo Alto VA: The Mens/Womens Trauma Recovery Program Outpatient clinics have developed a highly effective screening system involving screening local Veterans every two years for symptoms likely to be of clinical importance, including symptoms of PTSD. Clinicians in this Program are able to identify potential study participants. We intend to form a relationship with the Trauma Recovery Program. In addition, we intend to identify potential patients in the CPRS (Computerized Patient Record System). Patients with a diagnosis of PTSD will be identified and their primary healthcare provider will be approached and asked to introduce the study.

Two types of letters are attached; 1) "letter from study to veteran" which is a letter that can be sent directly from the study team to candidates when we have names and addresses of candidates who have already expressed an interest in the study and given permission to be contacted , and ii) "letter from healthcare provider to veteran" which is a letter that can be sent from any VA provider (e.g., pain clinic, etc) introducing the study to candidates.

2. OTHER VA STUDIES: We intend to recruit participants who have finished other studies and who have expressed an interest in being contacted about other studies. a) A PTSD, aging and genetics study study at the VA Palo Alto (P.I. Dr Jerry Yesavage). This group is an attractive population from which to recruit as no treatments are given, thus reducing any possibility of confounds with the current proposal. b) The PTSD Sleep Apnea Clinical Study (PI, Dr Lisa Konishita) is another ongoing study into PTSD at the VA Palo Alto from which we intend to recruit participants.

3. THE COMMUNITY: Study flyers will be posted at various locations including a) media advertisements, b) National Center for PTSD at the Menlo Park, c) Newsletter of the Center for Compassion and Altruism Research and Education at Stanford University, d) social media including Veterans Facebook service on

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

Facebook.

4. The study team may use mass mailing for recruitment purposes. Lists of Veterans enrolled at VA Palo Alto will be generated by the VA Office of Business Analytics. Lists may include 1) veterans with a diagnosis of PTSD or 2) all veterans regardless of PTSD status.

The study team will then send postcards (see Section 16: "postcard for mass mailing.PDF") to this list.

**h) Inclusion and Exclusion Criteria.**

**Identify inclusion criteria.**

1. Aged 18 years or older.
2. Veteran from armed forces.
3. Meet criteria for current PTSD as determined by a score of >38 on the PTSD Checklist-5 (PCL-5)(Weathers et al., 2013).

**Identify exclusion criteria.**

1. Participation in another concurrent clinical trial.
2. Unable to visit the VA Palo Alto for study visits.
3. Intention to begin a new course of Behavioral Therapy (e.g., Cognitive Behavioral Therapy including Prolonged Exposure or Cognitive Processing Therapy) during the study period.
4. Current or recent (<60 days) suicidal or homicidal intent at screening. Such patients will be referred for VA psychiatric care.
5. Mental disorders including schizophrenia, bipolar I, psychosis for any reason experienced within the prior six months.
6. Substance dependence (other than nicotine) within the prior thirty days,
7. Seizure disorder not well controlled
8. Severe traumatic brain injury.
9. Initiated psychotropic medication within 8 weeks prior to the initial screening. Excluded participants could be re-considered for eligibility after stability on medication was achieved.
10. In the opinion of the study clinical psychologist, the participant is not currently stable enough to receive treatment.

Involvement in other (non-behavioral) treatments will be tracked closely through self-report and clinician interviews. Study candidates who express imminent intent to harm self or others at any point in the study will be referred for VA emergency care. Participants who meet criteria for PTSD but are eliminated due to screening failure, or elect not to participate in this research program will be referred to their local VAMC mental health clinic.

**i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a waiver of authorization for recruitment (in section 15).**

The study coordinator will conduct a short phone screen to establish basic eligibility criteria. Data will include inclusion/exclusion criteria age, and verification of veteran status.

**j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.**

We will ask the potential subject if they are participating in any other protocols. They will be instructed not to participate in any other protocols during their involvement with our study without first getting prior authorization from both our research team and that of the other study. Overlapping participation will be handled on a case-by-case basis.

**k) Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations**

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

This study involves 2 parts: regular payment of \$400 for the standard part of the study and up to \$300 more for optional parts of the study; participant could receive \$800 total for participating in all parts of the study. Standard Study Phase

Participants receive \$400 if all visits and follow-ups are completed. They will receive a first payment of \$200 for successful completion of the treatment phase, and a second \$200 the end of the one year followup. Extra expenses for travel are not paid as these payments are intended to cover all expenses including travel and therefore do not constitute undue pressure to volunteer. These payments will be mailed. If participants withdraw from the study early, payment will be prorated for the proportion of the study completed.

#### Optional Study Phase

1. MRI \$50 will be paid for each session, baseline and end of treatment, total possible \$100.
2. EEG. \$50 will be paid for each session, baseline and end of treatment, total possible \$100.
3. \$100 will be paid for each sleep device session, totaling \$200.

Total optional study payment \$400

**l) Costs. Please explain any costs that will be charged to the participant.**

There are no costs to participants other than time and inconvenience.

**m) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.**

Duration of entire study: 4 years

Pre-screen, screen, consent: 2 hours.

For active participation in the study -

Baseline: 7 hours

Intervention (SKY): 5 days @ 3h/day + 5 wks @ 2h/wk = 25 h

Intervention (CPT): 6 wks @ 2h/wk = 12h

Overnight memory consolidation measures: 2 @ 2h each = 4h

Follow-up: visit @ 1 month and 12 months post treatment = 4h

Total time per participant (SKY group) = 42h

Total time per participant (CPT group) = 29h

Analysis of participant data: 12 months.

## 9. Risks

- a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

#### The risks of the Investigational devices.

No Investigational device used.

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

**The risks of the Investigational drugs. Information about risks can often be found in the Investigator's brochure.**

No investigational drugs used.

**The risks of the Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.**

n/a

**The risks of the Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).**

Monitoring heart rate. The sensor is usually attached with sticky patches and tape, which in a few individuals may cause skin irritations. Participant will be asked if they are allergic to adhesive tape. We will also use electrode gel to ensure good monitoring, which some individuals may find uncomfortable. EEG requires a cap to be worn which may be uncomfortable after a long period of time. Images that are shown may induce mild emotional responses such as fear, disgust, or sadness. MRI requires participants to remain still for up to one hour, which may be uncomfortable. We will attach the sleep recording device with electrodes to the face and scalp. The risks associated with recording sleep with the commercially available polysomnography are minimal. The main risk is that the taping or gluing of electrodes onto the scalp can cause contact dermatitis, a reddening of the skin. If this were to occur, we would recommend that participants put lotion on the area of the affected skin.

**The risks of the Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.**

No radioisotopes/radiation-producing machines will be used.

**The risks of the Physical well-being.**

See above, Procedures to be performed.

**The risks of the Psychological well-being.**

SKY Meditation: Pilot data was collected from 21 Veterans with PTSD treated with SKY and no specific risks or adverse events were encountered. On the basis of these data we estimate the foreseeable risks of SKY meditation as minimal.

CPT-C: (Cognitive Processing Therapy-"cognitive only") CPT-C was chosen because it has been shown to be one of the most effective treatments for PTSD. In general, there's little risk associated with CPT. Because it explores painful feelings, emotions and experiences, patients may feel emotionally uncomfortable at times. CPT may require patients to confront situations they would rather avoid. This can lead to temporary stress or anxiety. We have chosen CPT-C which excludes the written exposure component as this has been found to be equally effective as the full protocol in treating PTSD (Resick et al., 2008). I

Cognitive measures-The risks posed by cognitive measures (e.g., CANTAB computerized battery, overnight memory consolidation measures) are generally mild (e.g., frustration and mild fatigue).

Clinician administered scales of PTSD, psychiatric disorders, and self report measures of mood- The risks posed by these measures (e.g., Clinician Administered PTSD Scale, Mini-International Neuropsychiatric Interview, Beck Depression Inventory - II, Beck Scale for Suicide Ideation) are generally mild. However, some questions may be potentially distressing to the participants by causing them to think about trauma relating to them that may be anxiety-provoking or upsetting.

**The risks of the Economic well-being.**

n/a

**The risks of the Social well-being.**

Loss of confidentiality

**Overall evaluation of Risk.**

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

- b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research must be completed at this location and complete the [LINKFORINTERNATIONALRESEARCHFORM] International Research Form. If not applicable, enter N/A.**

n/a

- c) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.**

Loss of confidentiality.

Every precaution will be taken to minimize loss of confidentiality. A double lock system will be maintained within a locked office and locked file cabinet. All electronic data will be secured on an encrypted, password-protected database behind a VA firewall.

A psychiatric screening is performed during the screening visit using the Mini-International Neuropsychiatric Interview (M.I.N.I. 7.0) (Sheehan et al., 1997). This structured diagnostic interview was developed to screen for DSM-5 and ICD-10 psychiatric disorders. Any patient who expresses an active current suicidal intent or plan at any time will be referred to acute psychiatric service at the VA Palo Alto.

Under certain circumstances, additional eligibility screening will be conducted. If a participant completes an in-person screen several months before treatments are scheduled to begin and either narrowly meets or narrowly does not meet an inclusion or exclusion criterion, additional eligibility screening will be conducted. Namely, the participant will be contacted less than one month before treatment and re-assessed with regards to the inclusion or exclusion criterion in question. For example, a participant who met criteria for substance use disorder, moderate and expressed an intention to reduce use at the initial in-person screen would be re-contacted and assessed for severity of substance use disorder. Substance use disorder, moderate or severe is an exclusion criterion, but mild is not.

Treatment Risk: We have taken a number of precautions to ensure patient safety and minimize risk in the following ways; 1) The SKY meditation program will be taught by a qualified SKY meditation instructor with experience in the Veteran populations, 2) during the consent process, the study coordinator will describe the treatments to the patient, 3) it is possible that females, especially those having suffered from sexual trauma will not be comfortable with a group setting that includes males. To avoid this problem, we propose to run separate SKY groups for males and females. 4) the study personnel will include a qualified clinical psychologist familiar with safety procedures.

It is not proven that the Cognitive Processing Therapy-"cognitive only" (CPT-C) that we have chosen to use induces lower levels of emotion than the full CPT format which includes a written exposure component. However, we have chosen CPT-C in order to avoid potentially unnecessary emotional discomfort to participants.

MRI: The study staff are well trained to assure the safety of MRI scans and all patients are asked in advance of any risk factors for adverse events in the magnet, including but not limited to; pregnancy, history of metal work, implanted devices, metal piercings, surgical history, claustrophobia, panic attacks, etc. These questions will be asked again in the minutes immediately prior to the scan to assure redundancy and the capture of any changed information since the administration of the initial questionnaire prior to the patient arriving at the WRIISC for their assessments.

The MRI machine uses a strong magnet and radiofrequency magnetic field (s) to make images of the brain interior including the blood flow that provides us with a measure of brain activity. The scanning procedure is very much like an x-ray CT scan. Participants will be asked to lie on a long narrow couch for a certain amount of time (up to one hour) while the machine gathers data. During this time participants will not be

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

exposed to x-rays, but rather a radio frequency magnetic field. Participants will not feel this but will, however, hear repetitive tapping noises that arise from the radio antenna around the body. We will provide earplugs or earphones that participants will be required to wear. Participants will be instructed to keep their head still. The space within the large magnet in which they will lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling. Participants will be informed of all of this in the consent form and also that they can discontinue the exam at anytime.

**MRI Risks.** All forms of medical diagnosis and treatment - -whether routine or experimental - -involve some risk of injury. There are no known significant risks with this procedure at this time because the radiofrequency magnetic fields, at the strengths used, are thought to be without harm. The exception is if a participant were to have a cardiac pacemaker, or a certain type of metallic clip in the body (i.e., an aneurysm clip in your brain). All participants will complete questionnaires about metal in the body such as a pacemaker or aneurysm clips. A copy of this questionnaire is attached with the consent form in section 16.

There is a possibility that Participants will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, the participant will be informed, and will be able to discontinue the exam at any time. The radiofrequency magnetic fields do not cause harmful effects at the levels used in the MRI machine. Participants will be scanned in the 3.0T magnet, and dizziness and nausea may occur if the head is moved rapidly within the bore of the magnet. National and Stanford guidelines have been developed for these machines, and these recommendations will be followed. Some of the fMRI sequences used in this research study are experimental, and have not been approved by the FDA for clinical use.

There is a risk of heating from radiofrequency imaging coils and their cables, button response boxes and their cables, and the cables from monitoring devices that record physiologic processes such as heartbeats per minute or electrical activity of the brain. Participants will be informed of this and instructed to report any heating sensation immediately.

EEG risks are minimal and rare. Some participants experience redness of skin due to preparation and removal of skin debris prior to electrode placement. This is temporary.

**Siesta Device:** We will apply electrodes to the face and scalp according to clinical standards of practice. There is a possibility of developing a rash (Contact dermatitis) underneath the electrodes attached to your skin. Wearing electrodes might also be uncomfortable and make it more difficult to sleep. This device is the standard for recording in patient care and has no other known risks associated with using it.

- d) Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.**

The clinical trial will terminate after 4 years or when 76 participants have been through the protocol.

## 10. Benefits

- a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.**

Potential benefits are relief from symptoms of posttraumatic stress disorder and consequent improvement in quality of life. Testing procedures could reveal a medical condition that may not have been apparent and for which treatment is available.

## 11. Privacy and Confidentiality



**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

### Privacy Protections

- a) **Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).**

Participants will meet in a private interview room with a member of the study team to sign the consent form and discuss the protocol for the study. One of the study treatments (SKY: Sudarshan Kriya Yoga) is delivered as a group therapy which does not allow full anonymity to be maintained. This will be emphasized to participants before enrollment.

Self-report questionnaires will be completed in a private setting (e.g. at home) and handed to the study coordinator at the next visit. The heart rate monitor will be fitted in a private setting.

### Confidentiality Protections

- b) **Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers (see above). List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 15a.**

Full name  
Social Security Number (for VA hospital registration and payment)  
Mailing address (for appointment notices and to mail payment)  
Email address (backup communication)  
Telephone number (for communication)  
Date of birth (study metric)  
Date of visit  
Demographics  
Physiological and Cognitive test data  
Medical history  
Survey/questionnaire responses

- c) **You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See <http://med.stanford.edu/datasecurity/> for more information on the Data Security Policy and links to encrypt your devices.**

**Provide any additional information on ALL data security measures you are taking. You must use secure databases such as <https://researchcompliance.stanford.edu/panels/hs/redcap> RedCap. If you are unsure of the security of the system, check with your Department IT representative. Please see <http://med.stanford.edu/irt/security/> for more information on IRT Information Security Services and [http://www.stanford.edu/group/security/securecomputing/mobile\\_devices.html](http://www.stanford.edu/group/security/securecomputing/mobile_devices.html) for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in an locked environment.**

**By checking this box, You affirm the aforementioned. Y**

Data will be collected on paper and/or electronic forms and questionnaires, and entered into encrypted, password-protected databases located on physically secure VA servers behind a firewall.

All types of data collected will be de-identified according to the VHA

Privacy Handbook 1200.12. Each subject will be assigned a subject ID (SUBID). All personnel involved in this study will have successfully completed applicable VA, and Stanford training.



**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

All subject-level identifiable data will be treated as Protected Health Information (PHI) unless that data does NOT contain any of the data elements that HIPAA considers protected. No sensitive data or PHI will be stored on any device other than the secure server. Paper forms will be stored in locked file cabinets in locked offices.

Data from the study will be on a VA server located at VA Palo Alto, password protected, encrypted and no PHI will be present.

- d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.**

All types of data will be de-identified according to the VHA Privacy as described above (c)

- e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).**

The research team will have access to data.

- f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.**

A study code is assigned to a subject after they sign a consent form. This code is independent of any identifying information.

- g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.**

The code will be maintained by the PI, and will be available to appropriate members of the research team but kept in a locked file cabinet or in an encrypted, password-protected file on a physically secure, password protected computer at VA Palo Alto.

- h) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See <http://www.stanford.edu/group/security/securecomputing/>. Additionally, if you will be using or sharing PHI see <https://uit.stanford.edu/security/hipaa>**

No PHI will be transferred to anyone outside the established research team.

- i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?**

All research staff will complete and remain current with all required VA and Stanford training prior to working with human subjects. The PI will also reinforce the importance of maintaining confidentiality.

## 12. Potential Conflict of Interest

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

## Financial Interest Tasks

Investigators	Role	Email	Has Financial Interest?	Date Financial Interest Answered	Date OPACS Disclosure Submitted	Date OPACS Review Completed
Peter Bayley	PD	peter.bayley@va.gov	N	10/02/2020		
Jamie Marc Zeitzer	OP	jzeitzer@stanford.edu	N	10/02/2020		
Laura Lazzeroni	OP	Lazzeroni@stanford.edu	N	10/02/2020		
Walton T Roth	OP	wtroth@stanford.edu	N	10/02/2020		

## 13. Consent Background

### 13.1 Consent

### Consent for All Participants 11

**Sponsor's Consent Version Number: (if any) :**

- a) Describe the informed consent process. Include the following.
- Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)
  - When and where will consent be obtained?
  - How much time will be devoted to consent discussion?
  - Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
  - What steps are you taking to minimize the possibility of coercion and undue influence?
  - If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

i. Trained study personnel will be obtaining consent. All study staff will be trained and knowledgeable about the study. ii. After telephone screening (for which a Waiver of Authorization for Recruitment is being requested), consent will be the first component of participation in this study. Consent will be obtained in a private room at the study center. iii. 30 minutes is allotted to consent discussion, but it is possible that consent could take up to 60 minutes if needed. iv & v. First, the information contained in the written informed consent document is explained verbally to prospective participant in a language they can understand. Repetition is required during any learning process and is incorporated into the informed consent procedures. Special care is taken to repeatedly inform prospective participants that their participation is entirely voluntary and that they may withdraw at any time and for any reason without penalty or loss of currently existing benefits. Prospective participants are then asked to carefully read the written informed consent form, and any questions are answered. Next, the prospective participant is asked to summarize the consent form with special focus on the discomforts, risks, and confidentiality sections. When prospective participants have demonstrated (by stating in their own words) that they understand the purposes, risks, and benefits of the study, they are asked to sign and date the last page. The Study Staff and a witness also sign and date informed consent document, and the participant is given a copy for their records. The emphasis on the voluntary nature of participation is designed to minimize the possibility of coercion or undue influence on participation. vi. n/a

- b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter 12.2 for guidance.

Prospective participants will be asked to carefully read the written informed consent form, and any questions will be answered. Next, the prospective participant will be asked to summarize the consent form with special focus on the discomforts, risks, and confidentiality sections. When prospective participants have demonstrated (by stating in their own words) that they understand the purposes, risks, and benefits of the study, they will be asked to sign and date the last page. Understanding English is a requirement for this study

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

- c) **What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.**

All participants in this study must be able to independently consent to participate.

**Additional VA questions:**

- i) **List the people to whom you have formally delegated responsibility to obtain informed consent, and state whether they have the appropriate training to perform this activity.**

All study personnel (the PI, study coordinator, psychologist, research assistants) will be appropriately trained to obtain informed consent.

- ii) **Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative (LAR) or both? If LAR, is it clear who can serve as LAR?**

Legally effective informed consent will be obtained. Use of an LAR would exclude a participant from eligibility

- iii) **Will the circumstances of the consent process minimize the possibility of coercion or undue influence and provide the prospective participant or their representative sufficient opportunity to consider whether to participate?**

Minimization of the possibility of coercion or undue influence will be done by having prospective participants carefully read the written informed consent form, and any questions will be answered. Next, the prospective participant will be asked to summarize the consent form with special focus on the discomforts, risks, and confidentiality sections. When prospective participants have demonstrated (by stating in their own words) that they understand the purposes, risks, and benefits of the study, they are asked to sign and date the last page. The emphasis on the voluntary nature of participation is designed to minimize the possibility of coercion or undue influence on participation.

- iv) **Will the circumstances of the consent process minimize the possibility of coercion or undue influence?**

Minimization of the possibility of coercion or undue influence will be done by having prospective participants carefully read the written informed consent form, and any questions are answered. Next, the prospective participant is asked to summarize the consent form with special focus on the discomforts, risks, and confidentiality sections. When prospective participants have demonstrated (by stating in their own words) that they understand the purposes, risks, and benefits of the study, they are asked to sign and date the last page. The emphasis on the voluntary nature of participation is designed to minimize the possibility of coercion or undue influence on participation.

- v) **Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?**

No exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence is included.

- vi) **Please confirm the following:**

- A witness to the participant's signature or the participant's legally authorized representative's signature will sign and date the consent document.**
- If the sponsor or the IRB requires a witness to the consenting process in addition to the witness to the participant's signature and if the same person is needed to serve both capacities, a note to that effect is placed under the witness's signature line.**
- A copy of the signed and dated consent document will be given to the person signing the consent document.**
- The consent form is on the VA Form 10-1086.**

### 13.2 Waiver of Documentation Telephone Screen Script 6

**Sponsor's Consent Version Number: (if any) :**

- Describe the informed consent process. Include the following.**
  - Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)**

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

- ii) When and where will consent be obtained?
- iii) How much time will be devoted to consent discussion?
- iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
- v) What steps are you taking to minimize the possibility of coercion and undue influence?
- vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

The person obtaining consent will be one of the investigators, the study coordinator, or a research assistant, who have been trained to give informed consents. (ii) The consenting interview is always done after the potential participant has been presented with a description of the and has indicated interest in participating, and before any information is collected, or any questionnaires answered. The consenting interview typically takes place in one of the private interview rooms in War Related Illness and Injury Study Center (WRIISC). (iii) Enough time will be allowed for the consent discussion for the potential participant to make an informed decision, and to ask any and all questions they may have and discuss the study with researchers. We estimate this will take between 30 minutes and one hour. (iv) The potential participant may take the consent home to discuss with family and others, and return later to sign it if they so desire. (v) Every attempt will be made to ensure the participant does not feel coerced. We believe that the payment offered for participation is not great enough to entice a participant if they do not want to do so.

- b) **What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter 12.2 for guidance.**

The potential subject will be asked questions about the study to make sure they understand. All participants will have a good understanding of English. Hearing impairment severe enough to impair comprehension is an exclusion.

- c) **What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.**

If there is a question about a potential participant's capacity to give consent, he or she will be evaluated by a staff psychiatrist or psychologist at an in-person interview instead of a telephone screen.

#### Additional VA questions:

- i) **List the people to whom you have formally delegated responsibility to obtain informed consent, and state whether they have the appropriate training to perform this activity.**

The persons obtaining consent and administering the telephone screen will be one of the investigators, the study coordinator, or a research assistant, all of whom have been trained to give informed consents. All staff have completed the required training in Human Subjects, Good Clinical Practice, and HIPAA.

- ii) **Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative (LAR) or both? If LAR, is it clear who can serve as LAR?**

Consent for the phone screen will be obtained from the person answering the telephone interview questions. Legally effective informed consent will be obtained during their first site visit. Use of an LAR would exclude a participant from eligibility.

- iii) **Will the circumstances of the consent process minimize the possibility of coercion or undue influence and provide the prospective participant or their representative sufficient opportunity to consider whether to participate?**

Participants are allowed as much time as needed to discuss the project with the research staff. If desired by the participant, the telephone screen will be delayed for as long as needed to allow participants to discuss the project with family, personal health providers, or others. The participant will be encouraged to call back after discussing the study with family or friends.

- iv) **Will the circumstances of the consent process minimize the possibility of coercion or undue influence?**

The researcher will explain the interview to the potential participant and answer any questions they may have.

- v) **Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?**

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder  
**Approval Period:** 11/30/2020 - 11/30/2021

All information presented to the participant, including anything they must sign, has been approved by the IRB.

vi) Please confirm that the consent form is on the VA Form 10-1086

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

- 1) Y 45 CFR 46.117(c)(i). For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.
- 2) 45 CFR 46.117(c)(ii). For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
- 3) 45 CFR 46.117(c)(iii). For research not subject to FDA regulation, if subjects or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- 4) 21 CFR 56.109(c)(1). For research that is subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

**Rationale for above selection:**

Please see attached call script.

#### 14. Assent Background (less than 18 years of age)

#### 15. HIPAA Background

##### 15.1 Waiver of Authorization for telephone screen

###### Recruitment

- a) Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.

Full name Social Security Number (for VA hospital registration and payment) Mailing address (for appointment notices and to mail payment) Email address (backup communication) Telephone number (for communication) Date of birth (study metric) Date of visit Demographics Physiological Monitoring data Medical history and physical examination information Survey/questionnaire responses 1) Trained study personnel will be conducting screening. All will be trained and knowledgeable about the study. 2) Screening will happen on VA office phones, in a secure and private office setting, and every effort will be made to ensure that the potential research participant is in a private and comfortable environment at the time of screening. 3) 45 minutes is allotted for telephone screening, but it is possible that it could take additional time in order to answer participant questions as needed. 4) First, the information contained in the telephone screen is explained in language they can understand. Repetition is required during any learning process and is incorporated into the telephone screening procedures. Additionally, throughout the screening process participants are encouraged to ask questions, and screeners check to make sure everything is understood. Special care is taken to repeatedly inform prospective participants that their participation is entirely voluntary and that they may withdraw at any time and for any reason without penalty or loss of currently

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

existing benefits. The emphasis on the voluntary nature of participation is designed to minimize the possibility of coercion or undue influence on participation.

b) Please Answer:

Y **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**

Y **Do you certify that the research could not practically be conducted with out the waiver?**

Y **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**

Y **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

Information from the telephone screening will be protected from breach of confidentiality through several safeguards including password protected computers, locked offices, doors, and file cabinets, and secure computer networks as described previously.

d) **Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

The disposition of the research records will be consistent with VA research record retention policies. If potential participants are found to be ineligible for or uninterested in participation in the study, records will be securely maintained until such time as their destruction is allowed by an approved and published VA schedule of record retention

## 15.2 Waiver of Authorization for

## review of computerized health records

### Recruitment

a) **Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

For the purposes of recruitment trained study staff will review the CPRS (computerized patient record system) for records administered as part of previous medical and psychiatric evaluations including: • Medical history and physical examination information • Medication status • Progress notes • Mental health (not psychotherapy) notes • Psychological test results

b) Please Answer:

Y **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**

Y **Do you certify that the research could not practically be conducted with out the waiver?**

Y **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**

Y **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

Information from the chart review will be protected from breach of confidentiality through several safeguards including password protected computers, locked offices, doors, and file cabinets, and secure



---

**Title :** Breathing Meditation Intervention for Post-Traumatic Stress Disorder

**Approval Period:** 11/30/2020 - 11/30/2021

---

computer networks as described previously.

- d) **Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

The disposition of the records will be consistent with VA research record retention policies. If potential participants are found to be ineligible for or uninterested in participation in the study, records will be securely maintained until such time as their destruction is allowed by an approved and published VA schedule of record retention